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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,005	05/25/2000	Yoko Asakura	0010-1108-0 CONT	7631

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

10

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,005

Applicant(s)

ASAKURA ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 13 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12 and 14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

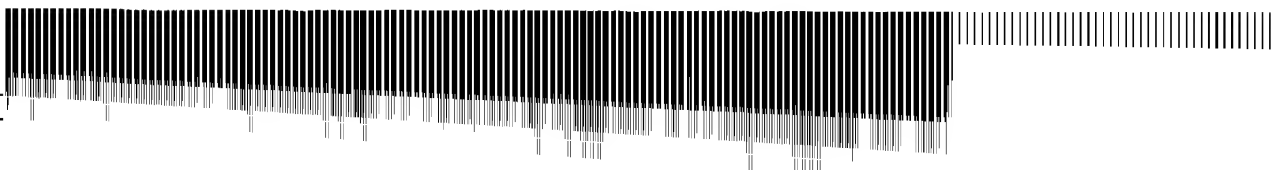
- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION*Status of the Application*

Claims 1-19 are pending.

Applicant's election with traverse of Group III, claims 12 and 14, in Paper No. 9, filed on 10/10/01 is acknowledged. Information Disclosure Statements in Papers No. 4 (with PTO form 1449), 5, 6, 7 are also acknowledged.

Applicant's traverse is on the ground(s) that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the identified groups or shown that a burden exists in searching all the claims. This is not found persuasive for the following reasons. First, the methods of Groups I, II, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of Group I is directed to a method of producing coryneform bacteria having an improved amino acid productivity, the invention of Group II is directed to a method of producing coryneform bacteria having an improved nucleic acid productivity, the method of Group VI is directed to a method of producing amino acids, and the method of Group V is directed to a method of producing nucleic acids. In the instant case the different methods of Groups I, II, V, and VI are not disclosed as capable of use together, comprise different steps, utilize different products, and produce different results. Secondly, the products of Groups III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention of Group



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III is directed to a glutamic acid synthase gene and a cell comprising said gene whereas the invention of Group IV is directed to an arginine synthase gene and a cell comprising said gene.

Each of these genes constitute a different nucleic acid molecule and encode a different protein with different functions. Thirdly, while it is true that the products of Groups III and IV are related to the methods of Groups I, II, V, and VI as product and method of use, they are patentably distinct inventions if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the genes of Group III and IV can have other uses such as probes or in gene therapy. Finally, it is erroneous to assume that a search of these distinct inventions is co-extensive, since the Examiner must search not only for different products but also for different methods which do not necessarily have overlapping steps.

The requirement is deemed proper and therefore is made FINAL.

Claims 1-11, 13, 15-19 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

1. The drawings have been reviewed and are approved by a draftsman under 37 CFR 1.84 or 1.152.
2. The abstract of the disclosure is objected to because of grammatical errors and use of improper idiomatic English. For example, "method of producing coryneform bacteria having an improved amino acid- or nucleic acid-productivity comprises the steps of" instead of "method of

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producing coryneform bacteria having improved amino acid or nucleic acid productivity comprising the steps of", "this method can construct a mutant capable" instead of "this method allows the construction of a mutant capable", etc. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to under 37 CFR 1.71 because of grammatical/typographical errors and use of improper idiomatic English. For example, "prompter" in line 11, page 9 of the specification, "specifrrfically" in line 20, page 11 of the specification, etc. Correction is required. Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed).

Claim Objections

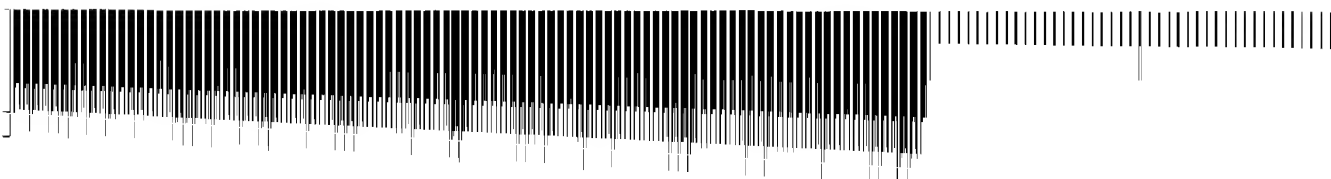
4. Claim 12 is objected to as being dependent on a claim drawn to a non-elected invention. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

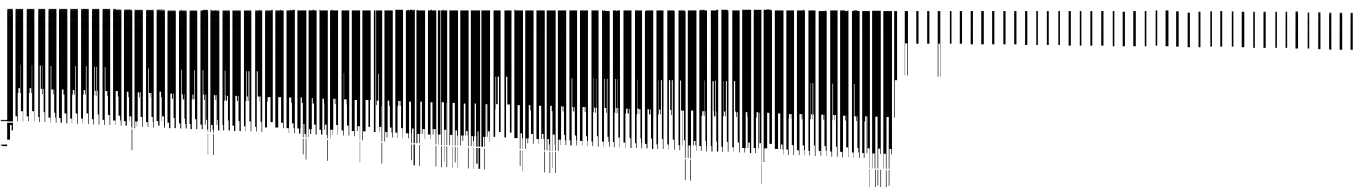
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 12 (claim 14 dependent thereon) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.



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6. Claim 12 is indefinite in the recitation of “gene having a promoter according to Claim 4” because claim 4 is directed to a method and not to a promoter. It is suggested that the portion of claim 4 directed to the promoter be incorporated in claim 12.
7. Claim 12 is indefinite in the recitation of “promoter for glutamate dehydrogenase (GDH) gene has a DNA sequence selected from the group consisting ofCGGTCA, TTGTCA, TTGACA, and TTGCCA “ as it is unclear how a promoter could only have six nucleotides. It is known in the art that promoters are longer than six nucleotides. Applicant has not provided the entire promoter sequence as recited in the claim. It is suggested that Applicant indicate the sequence being claimed by using a sequence identifier. See particularly 37 CFR 1.821.
8. Claim 12 is indefinite in the recitation of “the promoter for glutamate dehydrogenase (GDH) gene has a DNA sequence selected from the group consisting of (i) at least one DNA sequence” in claim 4 because it is not clear how can a promoter have more than one sequence. It is suggested that the term “at least one DNA sequence” be replaced with “a DNA sequence”.
9. Claim 12 is indefinite in the recitation of “DNA sequence selected from the group consisting of CGGTCA, TTGTCA, TTGACA, and TTGCCA in -35 region” in claim 4 as it is vague and confusing. As written, it is not clear what the relationship between the instant sequences and the -35 region is. If the listed sequences refer to the -35 consensus sequence, it is suggested that the language be modified to clearly indicate that any of the listed sequences can be the -35 consensus sequence.
10. Claim 12 is indefinite in the recitation of “TATAAT sequence or the same TATAAT sequence but in which the base of ATAAT is replaced with another base in -10 region” as it is



confusing language. It is not clear which base is being referred to and what the relationship between the sequence and the -10 region is.

11. Claim 12 is indefinite in the recitation of "(iii) a combination of (i) and (ii), wherein the sequence does not inhibit the function of the promoter" for the following reasons. First, it is unclear what combination is being referred to absent clarification of what is claimed in (i) and (ii). Second, it is not clear what sequence should not inhibit the function of the promoter: the sequence resulting from the combination of (i) and (ii) or the sequences listed in (i) or (ii).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 12 (claim 14 dependent thereon) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

13. Claim 12 is directed to any glutamic acid synthesizing gene having a promoter with a DNA sequence wherein the sequence does not inhibit the function of the promoter. No information has been provided as to which are the critical nucleotides which would inhibit the function of every promoter. The specification discloses examples of mutated promoters and how the activity of the glutamic acid dehydrogenase is affected by said mutations. This is insufficient to put one of skill in the art in possession of the claimed genus because this information is not sufficient to determine which nucleotides in every promoter will tolerate changes without

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affecting the promoter function. Thus, one of skill in the art cannot reasonably conclude that Applicant had possession of the claimed invention at the time the instant application was filed.

Claim Rejections - 35 USC § 102

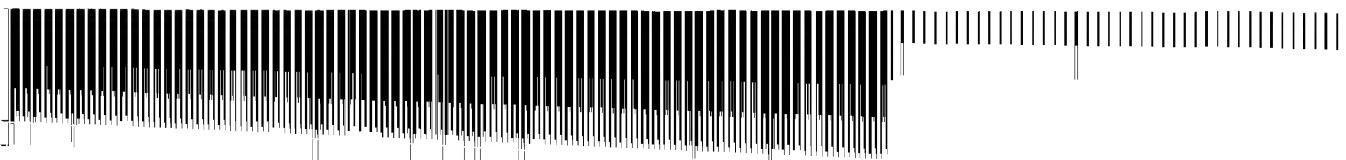
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 12 (claim 14 dependent thereon) is rejected under 35 U.S.C. 102(b) as being anticipated by Baggio et al. (GenEMBL accession number BTU82241, January 11, 1997) and Teller et al. (GenEMBL accession number CLOSGDHG, June 30, 1993). Baggio et al. discloses the nucleotide sequence of a glutamate dehydrogenase from *Bacteroides thetaiotaomicron* which comprises the sequence TTGACA (positions 233-238) within the promoter region before the coding sequence, which starts at position 301 (see attached alignment). Teller et al. discloses the nucleotide sequence of a glutamate dehydrogenase from *C. symbiosum* comprising the sequence TATAAT (positions 34-39) within the promoter region before the coding sequence, which starts at position 204 (see attached alignment). Therefore, Baggio et al. anticipates claim 12 (dependent on claim 4 (i)) and Teller et al. anticipates claim 12 (dependent on claim 4(ii)) as written.

15. No claim is in condition for allowance.



An examination of this application reveals that it includes a large number of vague, unclear, and/or missing terms, however, an examination on the merits has been performed. A detailed explanation of the problems found with this application has been provided in the paragraphs above. Applicant can provide clarification of these matters in response to this office action but should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed). Applicant is reminded that new art rejections can be applicable after a response to this office action is made and that such action can be made final.

Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

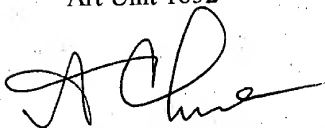
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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DR
December 13, 2001

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652



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